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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/534,867	10/28/2005	Tiziano Scubla	2503-1148	6915												
466 YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202	7590 12/31/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">WITHERSPOON, SIKARL A</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td colspan="2">1621</td></tr><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>12/31/2007</td><td>PAPER</td></tr></table>		EXAMINER		WITHERSPOON, SIKARL A		ART UNIT	PAPER NUMBER	1621		MAIL DATE	DELIVERY MODE	12/31/2007	PAPER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,867	<b>Applicant(s)</b> SCUBLA ET AL.	
	<b>Examiner</b> Sikarl A. Witherspoon	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The examiner has considered the amendment filed by applicants on November 30, 2007, and the arguments therein. The claims are still not in condition for allowance; as such, the following rejection is maintained and rewritten herein to reflect applicants' amendment.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treves et al (Environ. Sci. Technol., 2000), Droux et al (WO 98/25918) and Kirk-Othmer: Encyclopedia of Chemical Technology, vol. 10, 1993, all in combination.

The instant claims are drawn to a process for the separation of 1,4-butanediol mononitrate from a solution of 1,4-butanediol dinitrate and 1,4-butanediol, by extracting the mononitrate with water, and then extracting the mononitrate with a water-immiscible solvent.

Treves et al teach the preparation of 1,4-butanediol mononitrate (4-nitrooxy-1-butanol) by nitrating 1,4-butanediol followed by isolation by flash chromatography on silica gel (p 1198, method 1). While silent on the dinitrate, it would have been apparent

that some of the butanediol would have been nitrated such that at least small amounts of the dinitrate were produced in addition to the mononitrate.

The major difference between Treves et al and the instant claims is that Treves does not teach the claimed extraction to isolate 1,4-butanediol mononitrate.

Droux et al, however, teach that nitroxyalcohols are produced by nitrating the corresponding diol with nitric acid, in chloroform or trichloromethane, and then separating the nitroxyalcohol by first extracting with water, and then with an organic chlorinated solvent, in two consecutive extraction columns (prep. 1, 3, and 4).

The Encyclopedia of Chemical Technology teaches that for liquid-liquid extractions, such as that which taught by Droux et al, it is useful for multistage contacting (extractions) to be arranged in counter-current manner, especially for commercial-scale operations, for balance between high extract concentration and high degree of extraction of the solute (p 137).

In view of the combined reference teachings, it would have been obvious to a person having ordinary skill in the art to substitute the use of flash chromatography to separate the butanediol mononitrate, as taught by Treves, with a counter-current liquid-liquid extraction as suggested by Droux et al and The Encyclopedia. The butanediol monohydrate is an important intermediate in producing esters having pharmacological utility. Therefore, a person having ordinary skill in the art would have found it obvious to combine the above prior art in the manner suggested with desire to, and reasonable expectation of success in finding a technique for isolating the butanediol monohydrate that would afford the purest possible butanediol mononitrate.

### ***Response to Arguments***

Applicant's arguments filed November 30, 2007 have been fully considered but they are not persuasive. The thrust of applicants' arguments is that a person having ordinary skill in the art would not have substituted the flash chromatography taught by Droux with the counter-current liquid-liquid extraction suggested by Treves and Kirk-Othmer, and that Droux does not teach a purification process, but rather, teaches a common method for isolating a product from a reaction process.

The examiner does not find applicants' arguments persuasive, or material to the patentability of the instant claims. For one, the examiner respectfully disagrees with applicants' assertion that one would not have been motivated to substitute the separation technique taught by Droux with the extraction technique taught by Treves and Kirk-Othmer, and vice-versa. The examiner takes the position that since the references all teach a method wherein the butanediol mononitrate is separated, a person having ordinary skill in the art would want to employ any known separation technique that would afford an optimal concentration of the desired compound. Furthermore, the examiner would like to point out that like Droux, the instant claims recite a *separation* process, and do not expressly recite a *purification* process. Accordingly, the examiner finds the rejection of record proper.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sikarl A. Witherspoon whose telephone number is 571-272-0649. The examiner can normally be reached on M-F 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

saw

*Sikarl A. Witherspoon*  
SIKARL A. WITHERSPOON  
PRIMARY EXAMINER